



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,389	09/15/2004	Werner Zumbrunn	095473-0106	5388

22428 7590 09/09/2010
FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

MERCIER, MELISSA S

ART UNIT	PAPER NUMBER
----------	--------------

1615

MAIL DATE	DELIVERY MODE
-----------	---------------

09/09/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/711,389	Applicant(s) ZUMBRUNN ET AL.	
	Examiner MELISSA S. MERCIER	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-16, 19, 24, 25, 27-32, 36-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 18, 20-23, 26, 33-35 and 38-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7-1-10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 1, 2010 has been entered.

Claims 1-40 are pending in this application. Claims 1-16, 19, 24, 25, 27-32, 36-37 remain withdrawn from consideration. Claims 17-18, 20-23, 26, 33-35, and 38-40 are under prosecution in this application.

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed on July 1, 2010 is acknowledged. A signed copy is attached to this office action.

Withdrawn Rejections

Claim Rejections - 35 USC § 102

The rejection of claims 17-18, 20-23, 26, 35, and 38-39 under 35 U.S.C. 102(b) as being anticipated by Murdock (US Patent 6,374,136) has been withdrawn in view of Applicants extensive amendments to claim 17 to recite additional structural and

Art Unit: 1615

functional limitations including the location of the interface and a solvent removal system.

Claim Rejections - 35 USC § 103

The rejection of claims 33-34 under 35 U.S.C. 103(a) as being unpatentable over Murdock (US Patent 6,374,136) in view of Haak et al. (US Patent 5,993,435) has been withdrawn for the reasons indicated above.

Newly Applied Rejections

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 17-18, 20-23, 26, 33-35, and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pickup et al. (US 2003/0065294) in view of Frate (US Patent 6,211,296).

Pickup teaches a transdermal application device that comprises a dispenser to dispense bioactive compounds in liquid form on a transdermal patch to the skin, which reads on permeable interface for coupling to the porous surface (skin), and has a controller for automatically dispensing the bioactive agent on patch at a selected programmed time (a mechanism for causing the bioactive agent to be delivered) and can be programmed to a particular time of day or more than one time a day (abstract).

A spacer can be provided between the dispenser and cutaneous target (paragraph 0021). The dispenser comprises programmable microchip contains pre-

Art Unit: 1615

programmed information that is controlled by programmed computer to activate piezoelectric member to expel the bioactive material or liquid. The dispenser further comprises active agents in a replaceable container (a source of the bioactive agent that also is a waste reservoir when the delivery is completed).

The target for delivery is a patch that acts a reservoir, comprising the drug initially before delivery is complete. Figure 3 shows electronic programming of the device. The reference teaches collapsible reservoir that delivers bioactive agents. The device can deliver one or more than one drug at different times. Pickup discloses using the device to deliver bioactive agents such as nicotine to treat nicotine withdrawal (abstract; paragraphs: 0021-0023, 0040, 0045, 0050, 0060, 0061, 0065, 0069, claims, figures). The figures show the device encased within housing.

Although Pickup teaches the desire to remove excess bioactive agent to avoid undesired toxic effect if the drug is absorbed to the skin, see paragraph [0005], Pickup however, does not explicitly discuss the inclusion of a waste hydrogel reservoir.

However, the patch disclosed by Pickup absorbs the bioactive composition, and anything applied to this patch that does not get transdermally absorbed will remain in the patch, which then acts as a removable reservoir separated from the rest of the system.

Frate teaches hydrogel used to remove undesirable compounds of substrate by absorption of the waste to form single unite that can be removed and easily handled (column 1, lines 1-25). It is expected that the hydrogel expands when absorbs waste.

Art Unit: 1615

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide preprogrammed device to deliver bioactive agent to the skin comprising reservoir containing the agent and an interface patch on the skin as taught by Pickup, and further add a hydrogel absorbent layer to the interface patch as taught by Frate. One would have been motivated to do so because Pickup desired to avoid excess drug absorption and because Frate teaches that hydrogel can remove undesirable compounds from a substrate by absorption of the waste to form single unite that can be later removed and easily handled. One would reasonably expected formulating preprogrammed device to deliver bioactive agent to the skin comprising reservoir containing the agent and an interface patch on the skin and further the patch comprised hydrogel layer to absorb the waste and then easily and safely removed as single unit.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1617